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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,086	07/13/2001	En Li	0609.4560002	6968
26111	7590	03/10/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/720,086

Applicant(s)

LI ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-10,13 and 24-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 is/are allowed.
- 6) ☒ Claim(s) 1,3-10 and 24-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Arguments***

1. Claims 1, 3-10, 13 and 24-37 are pending.  
Claims 1 and 31 have been amended.  
Claims 1, 3-10, 13 and 24-37 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objections***

***Drawings***

3. The drawings submitted with the originally filed application are no longer objected.

***Claim Objections***

4. Claim 1(f) is no longer objected to because all the words included therein have been correctly spelled.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112***

5. The rejection of claim 24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

***Claim Rejections - 35 USC § 103***

6. The rejection of claim 13 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,492,168 (effective filing date April 22, 1998) is withdrawn.

***Priority***

7. Applicants submitted amendments to the Sequence Listing to reflect the correct nucleotide and amino acid sequence contained in the deposited clones, ATCC Deposit Nos. 209933, 209934 and 98809, which corresponds to SEQ ID NO: 1, SEQ ID NO: 2 and SEQ ID NO: 3, respectively.

Applicants have averred in previous Remarks submitted December 9, 2003 that these clones were deposited prior to the filing of the provisional applications and accordingly Applicants' claims should be afforded the filing dates of the provisional applications. Applicants argue in the Remarks submitted December 9, 2003 that "...Applicants' amendments to the sequences were minimal, the artisan would instantly comprehend that the resequenced polynucleotides were one in the same as the polynucleotides as described in the application as filed.", see Remarks, page 12, last paragraph. The Examiner has carefully reviewed these arguments, but find them unpersuasive.

Applicants have not supplied corroborative evidence that establishes that the sequences that have been resequenced are in fact one in the same as the deposited clones and that of the priority documents. It is suggested that Applicants submit a corroborative affidavit or declaration attesting and substantiating that the deposited

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clones are the same as those disclosed in the PCT and provisional applications. There continues to be insufficient proof suggestive that the proper sequences in the instant application and corresponding clones are one in the same as those listed in the priority documents. Moreover, the priority date afforded to claims 1, 3-10 and 24-37 is the instant application's filing date of July 13, 2001. Accordingly, since the method of claim 13 now encompasses the polynucleotides of claim 1 it is also afforded the July 13, 2001 priority date.

### ***Maintained Objections***

#### ***Specification***

8. The drawings originally filed with the specification continue to be objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure.

Applicants set forth that the polynucleotides shown in corrected Figures 1A, AB-1, 1C, 2A, 2B, 2C, 2B, 2C, 3A and 3B have adequate 35 U.S.C. 112, first paragraph support in the priority documents by reference to the deposits. For the reasons set forth in the Priority section the objection is maintained.

### ***Maintained Rejections***

#### ***Claim Rejections - 35 USC § 112***

9. The rejection claims 8 and 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants assert "The Examiner does not provide any reasoning for the rejection, merely stating that '[I]ines 7-25 of page 21 do not support that Applicants contemplated

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contiguous nucleotides of SEQ ID NO: 8 and 10 consisting of discrete fragments 50 and 100 nucleotides in length, respectively at the time of filing'. Applicants direct the Examiner's attention to page 21, lines 17-25. These points of view have been carefully considered found unpersuasive.

Remiss from Applicants' citation is the listing of the Examiner's explicit text that "[t]he Examiner has reviewed this section of the disclosure and does not concur with Applicants", see page 6, section 13, second paragraph of the Office Action mailed September 9, 2003 as Paper number 16. In essence what Applicants assert is support for the text in claims 8 and 10 is not sufficient. Furthermore, the text pointed out by Applicants continue not to support the unambiguous contemplation of at least 50 and 100 nucleotides. The text Applicants have pointed out does not support the exclusion of polynucleotides less than 50 nucleotides and 100 nucleotides for claims 8 and 10, respectively and accordingly the rejection is maintained.

10. The rejection of claims 1, 3-10 and 24-37 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claimed invention is maintained.

Applicants supply several Exhibits in support of their position that methods of making mutants are routine in the art and the construction of a mutant polypeptide is undue. Applicants also argue that "it is improper for the Examiner to reject the claims solely on the basis that the nucleotide fragments may not encode functional

polypeptides", see page 22, last paragraph of the Remarks. These Exhibits have been reviewed and the arguments have been considered but found unpersuasive.

Applicants have not supplied information relative to the use of these claimed mutants. While the making of the claimed polynucleotides may not be burdensome implementing these variants in the proposed applications of the specification may not be valid. As Applicants submit "the artisan will obtain mutants that have a range of activities", see page 20, first paragraph of the Remarks. The claims do not limit which particular functions the mutants should exhibit or preclude what functions they should or should not be able to perform. Notwithstanding, most of the claims suggest that a polypeptide will be produced. The specification continues to not provide sufficient guidance to enable one of ordinary skill in the art to make and use the claimed nucleic acids.

***Claim Rejections - 35 USC § 102***

11. The rejection claims 1, 3, 4, 8, 9, 24-26, 29-33, 36 and 37 under 35 U.S.C. 102(b) as being anticipated by Okano et al. (Nature Genetics 19:219 and 220, July 19, 1998), as evidenced by Accession numbers AF068625, AF068626 and AF068627 (December 6, 1999) is maintained.

Applicants argue that claims 31-37 are directed to polynucleotide of several ATCC Deposit numbers and the instant rejection should not be applied. And Applicants continue to assert they should be afforded a priority date that would preclude Okana as prior art. These points of view have been considered but found unpersuasive.

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For the reasons of record and listed in the instant Office Action the priority date afforded to claims 1, 3-10 and 24-37 is the instant application's filing date of July 13, 2001. And furthermore aside for the ATCC numbers these claims read on a nucleotide sequence complementary to a nucleotide sequence of ATCCs' nucleotides. Hence, the complementary sequences are not limited.

12. The rejection of claims 1, 3, 4, 8, 10, 24, 27-31, 34-37 under 35 U.S.C. 102(b) as being anticipated by Xie et al. (Gene 236(1): 87-95, 1999), as evidenced by Accession number AF067972 (February 12, 2001) is maintained.

Applicants argue that claims 31-37 are directed to polynucleotide of several ATCC Deposit numbers and the instant rejection should not be applied. And Applicants continue to assert they should be afforded a priority date that would preclude Okana as prior art. These points of view have been considered but found unpersuasive.

For the reasons of record and listed in the instant Office Action the priority date afforded to claims 1, 3-10 and 24-37 is the instant application's filing date of July 13, 2001. And furthermore aside for the ATCC numbers these claims read on a nucleotide sequence complementary to a nucleotide sequence of ATCCs' nucleotides. Hence, the complementary sequences are not limited.

### ***Claim Rejections - 35 USC § 103***

13. The rejection of claims 1, 3-10, 24-26, 29-33, 36 and 37 under 35 U.S.C. 103(a) as being unpatentable over Okano et al. (Nature Genetics 19:219 and 220, July 19,



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1998), as evidenced by Accession number AF068625 (December 6, 1999) and Xie et al. (Gene 236(1): 87-95, 1999), as evidenced by Accession number AF067972 (February 12, 2001), in view of Ausubel et al. (Current Protocols in Molecular Biology 2, Unit 16.8, see pp.16.8.1-16.11.6) is maintained for the reasons above and of record.

### ***Conclusion***

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne "Bonnie" Eyler, Ph.D. can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).  
ALANA M. HARRIS, PH.D.  
PRIMARY EXAMINER



Alana M. Harris, Ph.D.  
08 March 2004